

## REMARKS

Claims 1-4, 13-22 and 31-34 are presently pending in the case.

### Allowable Claims

Applicant acknowledges with appreciation the Examiner's indication that claims 13-22 and 31-34 are allowable.

### Claim rejections under 35 USC §112, first paragraph

The Examiner rejected claims 1-4 under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.* 325 F.3d 1306, 1319 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563.

An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). An Applicant may show possession of an invention by disclosure of drawings that are sufficiently detailed to show the Applicant was in possession of the claimed invention. *Vas-Cath*, at 1565. "[D]rawings alone may provide a 'written description' of an invention." *In re Wolfensperger*, 302 F.2d 950. "In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification." *Eli Lilly*, 119F.3d at 1568.

Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath*, at 1563.

In the present case, the Examiner has erroneously found that the addition of the term “only” in claim 1 in the amendment of December 22, 2011 constituted new matter and did not meet the written description requirement. According to the Examiner, “[t]here is no written description in the specification reciting that the powdered medicament exits the cavity only through the top end.” Applicant traverses this rejection.

That medicament exits the cavity only through its top end is described throughout Applicant’s specification as originally filed. For example, the discussions on page 3 lines 4-6, page 3 lines 10-12, page 3 lines 24-25, and numerous additional places throughout the specification make clear that the extraction occurs through the top end of the receptacle. Figure 4 and its associated discussion make clear that the extraction occurs only through the top end. Figure 4 tells a thousand words, as the saying goes, and some of those words are clearly that the medicament exits only through the top end. The explicit recitations mentioned above make clear the terminology and orientation.

After considering Figure 4 and the other relevant recitations in the specification, one of ordinary skill in the art would recognize that Applicant had possession of the invention as claimed in claim 1 at the time of filing. Accordingly, claim 1 does not introduce new matter and properly meets the written description requirement of 35 USC 112, first paragraph. Applicant requests withdrawal of the rejection.

### **35 USC §103(a)**

The Examiner rejected claims 1-4 under 35 USC §103(a) as being unpatentable over EP 1106196 to Ohki et al (hereinafter Ohki et al). The rejection is traversed.

Ohki et al does not render independent claim 1 unpatentable. Claim 1 is to a system comprising, inter alia, a dry powder inhaler and a receptacle. The receptacle comprises, inter alia, a top end and a bottom end, wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity, and wherein the raised central region is shaped to facilitate extraction of the powdered medicament when air or another gas is drawn through the cavity so that the powdered medicament exits the cavity only through the top end. Ohki et al does not disclose these features as claimed. For example, as shown in Figure 19, Ohki et al discloses powder outflow (H2) at both the top and the bottom of the blister. Since Ohki et al does not disclose each and every feature set forth in claim 1, it does render claim 1 unpatentable.

To make up for the deficiencies in Ohki et al in rendering claim 1 unpatentable, the Examiner goes on to posit that it would have been obvious to one of ordinary skill in the art to puncture only the top of the receptacle in Ohki et al. However, the Examiner provides no evidence, teaching or reasoning as to why this proposed modification would have been obvious to the person of ordinary skill. Accordingly, the Examiner has not satisfied the evidentiary burden of 35 USC 103(a) and has not established a prima facie case.

Contrary to the baseless assertion of the Examiner, one of ordinary skill in the art *would not* have found it obvious to make the Examiner's proposed modification of Ohki et al. Ohki et al discusses the advantages of the multi-hole arrangement throughout the specification. For example, note column 15's discussion of the creation of turbulent flow and the subsequent effective diffusion and micronization of the medicament in the receptacle. Because of these teachings, one of ordinary skill in the art would be taught away from making the Examiner's proposed modification.

For at least these reasons, claim 1 is not properly rejectable under 35 USC §103(a) as being unpatentable over Ohki et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in

the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Ohki et al could be modified, with a reasonable likelihood of success. There is no evidence to suggest that this is a situation where the ordinary artisan could have modified the teachings in a manner that would result in the invention of claim 1 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the reference cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 2-4 which depend from claim 1 and are not rendered unpatentable by Ohki et al for at least the same reasons as claim 1.

**Conclusion**

The claims are allowable for the reasons given above. Therefore, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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